

### **REMARKS/ARGUMENTS**

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

Claims 1-45 are pending in the application. The Examiner has designated Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 as drawn to the elected species and Claims 11-12, 14-15, 22-24, 34, 40, and 44-45 as withdrawn. Consistent with 37 C.F.R. §1.141, Applicant respectfully requests recombination of all of Claims 1-45 if, as argued below, the generic claims are found to be allowable.

Claims 1 and 30 have been amended to clarify that the hydrogel matrix is administered in liquid form and is solid at temperatures below about 33°C. This amendment is supported throughout the specification, and particularly at the bottom of page 6. As requested by the Examiner, Claims 26 and 42 have been amended to recite the full chemical name of EDTA; namely, ethylenediaminetetraacetic acid.

#### **I. Applicant's Information Disclosure Statement**

The Examiner has objected to the previously filed IDS, alleging that copies of the listed publications were not included and that a translation of DE 44 31 598 was not provided. Although Applicant received a stamped postcard indicating receipt of all documents included with the IDS, a copy of which is enclosed, in order to expedite consideration of these references, an additional copy is enclosed herewith. Applicant notes that a translation of the German document was included behind the German language original. Another copy of the translation is enclosed. Further, a clean copy of the IDS pages that contained citations that were not initialed by the Examiner is enclosed so that the Examiner may initial these references as officially considered.

#### **II. Claim Rejections – 35 U.S.C. §112**

Claim 26 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite due to the allegedly unclear definition of EDTA. As requested by the Examiner, Claim 26 and

similar Claim 42 have been amended to recite ethylenediaminetetraacetic acid, which is the commonly understood full name of EDTA. In light of these amendments, Applicant respectfully requests reconsideration and withdrawal of this rejection.

### III. Claim Rejections – 35 U.S.C. §102, first paragraph

Claims 1-2, 4, 7, 10, 25-26, and 28-29 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No.6,372,494 to Naughton *et al.* The Examiner alleges that Naughton teaches a method of stimulating hair growth using a hydrogel matrix composition comprising gelatin and a long chain carbohydrate, as well as amino acid such as glutamic acid, and EDTA. Applicant respectfully traverses this rejection.

The Naughton reference is directed to a method of forming a cell culture medium that has been conditioned by cells cultured therein. As taught in the reference, the conditioned cell culture medium contains extracellular proteins and cellular metabolites that are believed to imbue the media with pharmaceutical utility (see column 6, lines 27-32 and column 28, line 15 – column 32, line 8). Thus, it is the conditioned cell culture medium that the Naughton reference suggests has pharmaceutical utility, such as the ability to stimulate hair growth.

However, the cited reference fails to teach or suggest any particular pharmaceutical utility for the composition that the Examiner relies upon as containing collagen and dextran. Instead, the Examiner is relying upon sections of the application that disclose the manner in which the cell culture media is conditioned. Specifically, the Examiner is relying upon sections of the disclosure that describe a three-dimensional framework that is used as a scaffold providing attachment sites for cells as they condition the cell culture media (see column 6, lines 43-50). It is the three dimensional scaffold that may contain collagen, gelatin, or dextran (column 11, lines 54-67). However, this three-dimensional structure is not considered to have any pharmaceutical utility whatsoever in the Naughton reference. Instead, the three dimensional framework is clearly intended to be removed before use of the resulting cultured media for pharmaceutical use. As noted in columns 19 and 20 of the Naughton reference, the conditioned media is recovered by, for example, pumping it out of the media conditioning system, prior to further use of the conditioned media. Thus, it is clear that the three dimensional scaffold, which is the only source

of any teachings with regard to gelatin and dextran, is not used in any pharmaceutical application, and is certainly not taught to be useful for stimulating hair growth. In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 1-2, 4, 7, 10, 16-17, 25-26, 28, 30, 33, 35-36, and 41-42 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,238,888 to Gentz *et al.* The Examiner relies upon the Gentz reference as teaching a formulation to stimulate hair follicle production comprising collagen, dextran, glutamic acid, cysteine and EDTA. Applicant respectfully traverses this rejection.

The Gentz reference is directed to various formulations designed to deliver keratinocyte growth factor-2 (KGF-2). The reference discloses, for example, liquid formulations, thickened and gel formulations, and lyophilized formulations. The sections relied upon by the Examiner as relevant to the use of dextran and gelatin are within the portion of Gentz discussing thickened and gel formulations. The Gentz patent merely lists gelatin and dextran in a long laundry list of gelling agents and there is no suggestion to combine those two components in the same formulation. Applicants note that the Gentz patent does not provide any exemplary gel formulations that include either ingredient, much less the two together. For this reason, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Further, the Gentz reference requires that the gelling agents used in the gel formulations taught therein produce a formulation that remains liquid at room temperature and solidifies when applied to the surface of the skin (at about 37°C) (see column 8, lines 53-59). Although the Gentz reference suggests dextran and gelatin as possible gel forming high molecular weight compounds, it only suggests the use of such compounds in gel compositions that exhibit reverse thermal gelation behavior as described above. Thus, the Gentz reference clearly only teaches gel formulations wherein the gel increases in viscosity with increases in temperature (see column 9, lines 52-60). As noted above, the independent claims of the present application have been amended to recite that the hydrogel matrix of the invention is administered in liquid form and is solid at temperatures below 33°C. This is directly contrary to the teachings of the Gentz reference, which requires thermoreversible gelation behavior wherein the gelling agents provide

a formulation that is liquid at room temperature, but solidifies at physiologic temperature. Thus, the Gentz reference actually teaches away from the presently claimed invention and Applicants respectfully request reconsideration and withdrawal of this rejection on this basis as well.

#### IV. Claim Rejections – 35 U.S.C. §103

Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the above-described Naughton reference in view of U.S. Patent No. 6,046,160 to Obi-Tabot. The Naughton reference is relied upon as discussed above. The Obi-Tabot reference is relied upon as suggesting the use of denatured collagen. Applicant respectfully traverses this rejection.

As noted above, the portions of the Naughton reference relied upon by the Examiner as teaching a composition comprising gelatin or dextran are irrelevant to the pending claims. The pending claims are directed to a method of stimulating hair growth by administering a hydrogel matrix comprising gelatin and a long chain carbohydrate. In contrast, the Naughton reference does not teach any composition comprising gelatin and a long chain carbohydrate that has any pharmaceutical usefulness. Instead, the disclosure relied upon by the Examiner is actually directed to ingredients of a three dimensional framework that is used as a scaffold for cells. The cells are used to condition a cell culture media and the media itself is then suggested for use in pharmaceutical applications. However, there is no suggestion in Naughton that a three dimensional framework that comprises gelatin or dextran has any pharmaceutical use. It is clearly intended only as a scaffold during the incubation of the cells that are used to condition the media. The conditioned media is then separated from other components and used for various pharmaceutical purposes. It is the media only that Naughton suggests in column 31 would be useful for stimulating hair growth. There is nothing in the Naughton reference to suggest a hydrogel matrix comprising gelatin and a long chain carbohydrate would be useful in any pharmaceutical application whatsoever, much less in a treatment designed to stimulate hair growth. In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1-10, 13, 16-21, 25-28, 30-33, and 41-42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the above-described Gentz reference in view of the above-described Obi-Tabot reference. The Examiner relies upon the Gentz reference as noted above and relies upon the Obi-Tabot reference as teaching the use of denatured collagen. Applicant respectfully traverses this rejection.

As noted previously, the Gentz reference does not fairly teach or suggest the combination of gelatin and dextran, and only describes gel formulations that exhibit thermoreversible gelation characteristics, meaning the formulation remains liquid at room temperature and solidifies when applied to the surface of skin (i.e., solidifies at body temperature). Although the Gentz reference discloses dextran and gelatin in a long laundry list of gel forming high molecular weight compounds, there is no suggestion in the Gentz reference to combine the two components and certainly no suggestion to form a hydrogel matrix that is intended to be administered in liquid form, but which is solid at lower storage temperatures, such as below about 33°C. Instead, the Gentz reference very clearly teaches away from such a composition by suggesting that the gel formulations described therein exhibit thermoreversible gelation behavior where viscosity increases as temperature increases. This is directly contrary to Applicant's claimed invention and, as a result, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of the above-described Gentz, Obi-Tabot, and Naughton references. All of the references are relied upon as discussed above. Applicant respectfully traverses this rejection.

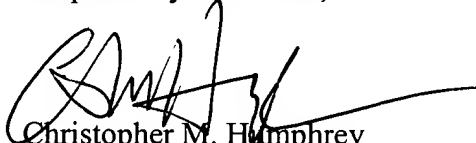
As noted above, the Naughton reference is completely irrelevant to the presently claimed invention and for this reason alone, this rejection is inappropriate and Applicant respectfully requests reconsideration and withdrawal thereof. As further noted above, the Gentz reference actually teaches away from the presently claimed invention by suggesting a gel composition that is liquid at room temperature, but which gels at higher temperatures. This is clearly contrary to the plain language of Applicant's claimed invention, and in fact represents a teaching away from

the present invention. For this reason, Applicant respectfully requests reconsideration and withdrawal of this rejection.

It is believed that all pending claims are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

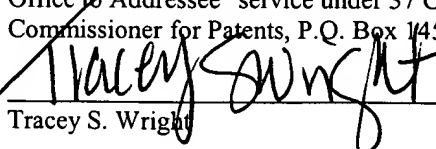


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"Express Mail" mailing label number EV 387076961 US  
Date of Deposit May 14, 2004

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